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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/894,912	06/28/2001	Y. Tom Tang	30266/37260A	4685

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EXAMINER	
BUNNER, BRIDGET E	
ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 12/18/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/894,912	TANG ET AL.	
	Examiner	Art Unit	
	Bridget E. Bunner	1647	

-- The MAILING DATE of this communication appears on the cover sheet with th correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 August 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-74* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-74* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

It is noted to Applicant that claim 71 is missing from the originally filed application and 37 CFR § 1.126 has been applied to renumber the claims in consecutive order. Therefore, originally filed claims 72-74 have been renumbered as claims 71-73.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   A. Claims 1-21, 40, 44, 70 and 72, drawn to an isolated polynucleotide encoding a polypeptide having stem cell growth factor activity, an expression vector, a host cell system, and a method of producing a polypeptide, classified in class 536, subclass 23.1.

   B. Claims 22-39, 41, 43, 71 and 73, drawn to an isolated polypeptide, classified in class 530, subclass 350.

   C. Claim 42, drawn to a culture medium comprising an amount of a polypeptide effective to maintain survival of or promote proliferation of a stem cell or germ cell, classified in class 435, subclass 404.

   D. Claims 46-50, drawn to an antibody that binds a polypeptide, classified in class 530, subclass 387.1.

   E. Claim 51, drawn to a method for detecting a polynucleotide in a sample comprising contacting the sample with a compound that binds to and forms a complex with the polynucleotide, classified in class 435, subclass 6.

   F. Claim 52, drawn to a method for detecting a polynucleotide in a sample comprising contacting the sample under stringent hybridization conditions with nucleic acid primers to anneal the polynucleotide, classified in class 435, subclass 6.

   G. Claim 54, drawn to a method for detecting the polypeptide in a sample, classified in class 435, subclass 7.1.

   H. Claim 55, drawn to a method for identifying a compound that binds to the polypeptide comprising contacting the compound with the polypeptide for a time sufficient to form a polypeptide/compound complex, classified in class 435, subclass 7.1.

I. Claim 56, drawn to a method for identifying a compound that binds to the polypeptide comprising contacting the compound with the polypeptide in a cell for a time sufficient to form a polypeptide/compound complex wherein the complex drives expression of a reporter gene sequence, classified in class 435, subclass 7.1.

J. Claims 57-59, drawn to a nucleic acid array, classified in class 435, subclass 6.

K. Claims 60-61, drawn to a method of treatment of a subject in need of enhanced/decreased activity or expression of stem cell growth factor-like polypeptide comprising administering the subject a composition comprising a therapeutic amount of an agonist, classification dependent upon structure of agonist.

L. Claims 60-61, drawn to a method of treatment of a subject in need of enhanced/decreased activity or expression of stem cell growth factor-like polypeptide comprising administering the subject a composition comprising a therapeutic amount of a polypeptide, classified in class 514, subclass 2.

M. Claims 60-61, drawn to a method of treatment of a subject in need of enhanced/decreased activity or expression of stem cell growth factor-like polypeptide comprising administering the subject a composition comprising a therapeutic amount of a polynucleotide, classified in class 514, subclass 44.

N. Claims 62-65, drawn to a method of supporting proliferation or survival of a stem cell or germ cell comprising contacting said cell with an amount of a polypeptide, classified in class 435, subclass 4.

O. Claims 66-69, drawn to a stromal cell genetically engineered to express a polypeptide, classified in class 435, subclass 455.

The inventions are distinct, each from the other because of the following reasons:

a. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons. Groups A-D, and O are directed to products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct. Further, the protein of Group B can be prepared by processes which are materially

different from recombinant DNA expression of Group A, such as by chemical synthesis, or by isolation and purification from natural sources. Additionally, the DNA of Group A can be used other than to make the protein of Group B, such in gene therapy or as a probe in nucleic acid hybridization assays. The protein of Group B can be used in materially different methods other than to make the antibody of Group D, such as in therapeutic or diagnostic methods (e.g., in screening). Although the antibody of Group D can be used to obtain the DNA of Group A it can also be used in materially different methods, such as in various diagnostic (e.g., as a probe in immunoassays or immunochromatography), or therapeutic methods. The culture medium of Group C is structurally and functionally different from the products of Groups A-B, D, and O and can comprise a polypeptide other than the polypeptide of Group B. Finally, the genetically engineered stromal cell of Group O is structurally and functionally different from the products of Groups A-D and can comprise a polynucleotide and polypeptide other than those of Groups A and B.

b. Similarly, although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods constitute patentably distinct inventions for the following reasons. Inventions E-N are different methods because they require different ingredients, process steps, and endpoints. Groups E-N are different methods requiring different method steps, wherein each is not required, one for another. For example, Invention E requires search and consideration of contacting a sample with a compound that binds to and forms a complex with a polynucleotide and detection of the complex, so that if a complex is detected, the polynucleotide is detected, which is not required by the other inventions. Invention F requires search and consideration of contacting a sample under stringent hybridization conditions with nucleic acid primers that anneal to a polynucleotide, amplifying a product, and detecting said product and thereby the polynucleotide in the sample, which is not required by the

other inventions. Invention G requires search and consideration of contacting a sample with a compound that binds to and forms a complex with the polypeptide and detection of the complex, so that if a complex is detected, the polypeptide is detected, which is not required by the other inventions. Invention H requires search and consideration of identification of a compound that binds to a polypeptide by contacting the compound with the polypeptide, formation of a polypeptide/compound complex, and detection of the complex, which is not required by the other inventions. Invention I requires search and consideration of identification of a compound that binds to a polypeptide by contacting the compound with the polypeptide in a cell, formation of a polypeptide/compound complex, and detection of the complex by detection of reporter gene sequence expression, which is not required by the other inventions. Invention J requires search and consideration of placing a nucleic acid molecule of interest onto a surface, which is not required by the other inventions. Invention K requires search and consideration of efficacy of treatment of a subject in need of enhanced/decreased activity or expression of stem cell growth factor-like polypeptide by administration of a composition comprising an agonist of the polypeptide, which is not required by the other inventions. Invention L requires search and consideration of efficacy of treatment of a subject in need of enhanced/decreased activity or expression of stem cell growth factor-like polypeptide by administration of a composition comprising a polypeptide, which is not required by the other inventions. Invention M requires search and consideration of efficacy of treatment of a subject in need of enhanced/decreased activity or expression of stem cell growth factor-like polypeptide by administration of a composition comprising a polynucleotide, which is not required by the other inventions. Invention N requires search and consideration of contacting a stem cell or germ cell with a polypeptide to maintain survival of or promote proliferation said cell, which is not required by the other inventions.

c. Inventions A and E/F/J/M are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, In the instant case, the product claimed can be used in materially different processes, such as DNA purification.

d. Inventions B and G/H/I/L/N are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product claimed can be used as an antigen for the production of antibodies.

e. Inventions A and G/H/I/K/L/N are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions of Groups A and G/H/I/K/L/N are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions G/H/I/K/L/N do not recite the use or production of the polynucleotide of Invention A.

f. Inventions B and E/F/J/K/M are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions of Groups B and E/F/K/M are unrelated product and methods, wherein each is not required,

one for another. For example, the claimed methods of Inventions E/F/K/M do not recite the use or production of the polypeptide of Invention B.

g. In the instant case, the different inventions of Groups C/D/O and E/F/G/H/I/J/K/L/M/N are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions E/F/G/H/I/J/K/L/M/N do not recite the use or production of the culture medium, antibody, nucleic acid array, or stromal cell of Inventions C/D/O.

2. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their separate search requirement, different classification, and recognized divergent subject matter, restriction for examination purposes as indicated is proper.

3. Restriction to one of the following inventions is also required under 35 U.S.C. 121:

Group 1. The inventions as they pertain to the nucleotide sequence of SEQ ID NO: 9, classification dependent upon the nature of the inventions.

Group 2. The inventions as they pertain to the nucleotide sequence of SEQ ID NO: 11, classification dependent upon the nature of the inventions.

Group 3. The inventions as they pertain to the nucleotide sequence of SEQ ID NO: 12, classification dependent upon the nature of the inventions.

Group 4. The inventions as they pertain to the nucleotide sequence of SEQ ID NO: 31, classification dependent upon the nature of the inventions.

Group 5. The inventions as they pertain to the nucleotide sequence of SEQ ID NO: 33, classification dependent upon the nature of the inventions.

Groups 6-10. The inventions as they pertain to the nucleotide sequences of SEQ ID NO: 9, 11, 12, 31, or 33 respectively, wherein the polynucleotide sequence does not consist of SEQ ID NO: 47, classification dependent upon the nature of the inventions.

Group 11. The inventions as they pertain to a polynucleotide encoding a polypeptide which has an amino acid sequence comprising at least amino acid residues 22-279 of SEQ ID NO: 32, classification dependent upon the nature of the inventions.

Group 12. The inventions as they pertain to a polynucleotide encoding a polypeptide which has an amino acid sequence comprising at least amino acid residues 22-274 of SEQ ID NO: 34, classification dependent upon the nature of the inventions.

Group 13. The inventions as they pertain a polynucleotide which comprises at least nucleotides 574-1347 of SEQ ID NO: 31, classification dependent upon the nature of the inventions.

Group 14. The inventions as they pertain to a polynucleotide which comprises at least nucleotides 321-1074 of SEQ ID NO: 33, classification dependent upon the nature of the inventions.

Group 15. The inventions as they pertain to a polynucleotide comprising the protein coding cDNA insert of the plasmid deposited with the National Institute of Bioscience and Human-Technology under accession number FERM BP-7198, classification dependent upon the nature of the inventions.

Group 16. The inventions as they pertain to a polynucleotide comprising the protein coding cDNA insert of the plasmid deposited with the National Institute of Bioscience and Human-Technology under accession number FERM BP-7197, classification dependent upon the nature of the inventions.

The inventions are distinct, each from the other because of the following reasons:

h. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons. Each of the nucleotide sequences of Groups 1-16 is a unique nucleotide sequence, requiring a unique search of the prior art. Searching all of the sequences in a single patent application would provide an undue search burden on the examiner and the USPTO's resources because of the non-coextensive nature of these searches.

Because these inventions are distinct for the reasons given above and have acquired separate status in the art as shown by their separate search requirements, restriction for examination purposes as indicated is proper.

4. Restriction to one of the following inventions is also required under 35 U.S.C. 121:

Group 16. The inventions as they pertain to the amino acid sequence of SEQ ID NO: 10, classification dependent upon the nature of the inventions.

Group 17. The inventions as they pertain to the amino acid sequence of SEQ ID NO: 13, classification dependent upon the nature of the inventions.

Group 18. The inventions as they pertain to the amino acid sequence of SEQ ID NO: 16, classification dependent upon the nature of the inventions.

Group 19. The inventions as they pertain to the amino acid sequence of SEQ ID NO: 32, classification dependent upon the nature of the inventions.

Group 20. The inventions as they pertain to the amino acid sequence of SEQ ID NO: 34, classification dependent upon the nature of the inventions.

Groups 21-25. The inventions as they pertain to the amino acid sequences of SEQ ID NOs: 10, 13, 16, 32, or 34, respectively, wherein the polypeptide does not consist of SEQ ID NO: 48, classification dependent upon the nature of the inventions.

Groups 26-30. The inventions as they pertain to the amino acid sequences of SEQ ID NOs: 10, 13, 16, 32, or 34, respectively, wherein the C-terminal amino acid sequence does not comprise the amino acid sequence of SEQ ID NO: 46, classification dependent upon the nature of the inventions.

Group 31. The inventions as they pertain to a polypeptide which has an amino acid sequence comprising at least amino acid residues 22-279 of SEQ ID NO: 32, classification dependent upon the nature of the inventions.

Group 32. The inventions as they pertain to a polypeptide which has an amino acid sequence comprising at least amino acid residues 22-272 of SEQ ID NO: 34, classification dependent upon the nature of the inventions.

Groups 33-35. The inventions as they pertain to a polypeptide having at least 90% identity with SEQ ID NOs: 10, 13, or 16 and lacking amino acid sequence SEQ ID NO: 29, classification dependent upon the nature of the inventions.

Group 36. The inventions as they pertain to the amino acid sequence of SEQ ID NO: 27 classification dependent upon the nature of the inventions.

Group 36. The inventions as they pertain to the amino acid sequence of SEQ ID NO: 28 classification dependent upon the nature of the inventions.

Group 37. The inventions as they pertain to a polypeptide expressed by a polynucleotide comprising the protein coding cDNA insert of the plasmid deposited with the National Institute of Bioscience and Human-Technology under accession number FERM BP-7198, classification dependent upon the nature of the inventions.

Group 38. The inventions as they pertain to a polypeptide expressed by a polynucleotide comprising the protein coding cDNA insert of the plasmid deposited with the National Institute of Bioscience and Human-Technology under accession number FERM BP-7198, classification dependent upon the nature of the inventions.

The inventions are distinct, each from the other because of the following reasons:

i. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons. Each of the amino acid sequences of Groups 16-38 is a unique amino acid sequence, requiring a unique search of the prior art. Searching all of the sequences in a single patent application would provide an undue search burden on the examiner and the USPTO's resources because of the non-coextensive nature of these searches.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their separate search requirements, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

In order to be fully responsive, Applicant must select one from Invention from Groups A-O, one nucleotide sequence from Groups 1-15, and one amino acid sequence from Groups 17-38. Applicant is advised that A-O, 1-15, and 17-38 are not species election requirements; rather, each of A-O, 1-15, and 17-38 is a restriction requirement.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bridget E. Bunner whose telephone number is (703) 305-7148. The examiner can normally be reached on 8:30-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 872-9305.

BEB
Art Unit 1647
December 13, 2002

Gary L. Kunz
GARY KUNZ
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